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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/180,335 | 02/25/1999 | ALAN DEREK COOKSON | P/222-45 | 6668 |

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EXAMINER

SNAY, JEFFREY R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1743

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/180,335

Applicant(s)

COOKSON ET AL.

Examiner

Jeffrey R. Snay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-18 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 12-14 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-5, 7, 12, 13 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al (US 5,420,042) in view of Tosa (EP 0667528), and further in view of Carter et al.

Schafer et al disclose a method for detecting an analyte in a reaction, such as an immunological binding reaction. A calibration curve is created by continuously measuring the kinetic change of absorbance over time for a number of different standard samples of known concentration (column 5, lines 49-53). The calibration kinetic data is manipulated such that a functional relationship is drawn between analyte concentration and an input variable or "discriminator" (column 6, lines 4-14). The input variable can be, among others, the absorbance value at a particular measuring time (column 7, lines 16-23, and the paragraph bridging columns 7 and 8). To determine the concentration of an unknown sample, the sample is subjected to the same specific binding reaction as were the calibration samples and the absorbance monitored continuously to yield the kinetic response curve of the unknown sample. Discriminators are continuously determined and concentrations are calculated continuously for the sample from the operative discrimination algorithm obtained from the calibration function relating concentration to measuring time and absorbance measurement (column 9, line 63 to column 10, line 11).

With respect to instant claims 17 and 18, Schafer et al describe the method as comprising conducting the kinetic measurements until a plateau is reached, i.e. a steady state (see e.g. Figure 1). However, it is also described in Schafer et al that use of end point data is not required (column 6, lines 26-29), and that the unknown

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concentrations as well as calibration data can be determined from data points obtained during the kinetic reaction phase, such as values at particular times, slope, curvature and roughness values (column 7, lines 16-23).

The method of Schafer et al differs from the claimed invention in that it performs the immunoreactions in solution rather than on a solid surface. However, Tosa discloses a similar kinetic measurement of a specific immunochemical binding reaction on a waveguide surface in order to enable the monitoring of the reaction by luminescence detection. Such luminescence detection was notoriously well known in the art of immunological testing as advantageous for enabling rapid, real time and fast determination of binding reactions, as evidenced by the disclosure of Carter et al (columns 1-2). It would have been obvious to one of ordinary skill in the art to substitute the heterogeneous method and luminescence detection of Tosa for the homogeneous absorbtion detection of Schafer et al as an art recognized equivalent method for detecting a binding reaction as well as providing the desired capabilities of fast detection response and simplified detector design.

5. Claims 6 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al, in view of Tosa, as applied to claim 1 above, and further in view of Sutherland et al.

The reasons for this rejection are set forth in paragraph 5 of the previous Office action, paper no. 15.

Response to Arguments

6. Applicant's arguments filed 12-09-2002 have been fully considered but they are not persuasive.

Applicant traverses the rejection on the grounds that no motivation is found to combine the references. This argument was fully addressed in the last Office action. Furthermore, it is noted that Schafer et al, the primary reference, itself discloses the application of the method to a heterogeneous system involving binding to solid latex particles. See Example 2).

Applicant further traverses the rejection on the ground that Schafer et al fails to teach continuous monitoring of concentration. Initially, it is noted that the instant claims contain no such limitation. For example, instant claim 1 merely recites that the analyte dependent kinetic data is measured continuously. The claim then recites that the measured kinetic data is "manipulated to quantitatively determine an unknown sample". The results of that determination are monitored continuously. Thus the language of the claims are recited broadly, and nowhere positively require that the concentration be measured on a continuous basis. In any even, Schafer et al teach continuous measurement of an analyte dependent parameter, and the continuous determination discriminators based on the measured analyte dependent parameter. Column 10, first full paragraph. Thus the analyte dependent parameter is measured continuously and further is "manipulated" to determine an unknown sample. The presently recited step of continuously determining an unknown sample is present in Schafer as the continuous determination of discriminators, which are taught as directly correlated to the analyte.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Election/Restrictions

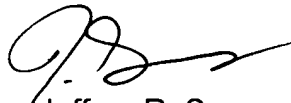
8. This application contains claims 8-11, drawn to an invention nonelected with traverse in Paper No. 7. **A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.**

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Snay whose telephone number is (703) 308-4032. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jeffrey R. Snay
Primary Examiner
Art Unit 1743

jrs
November 17, 2003